Exhibit A

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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, *et al.*, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	No. 1:23-cv-03026 DEFENDANTS' MOTION FOR CLARIFICATION 05/10/23 WITHOUT ORAL ARGUMENT

Plaintiffs challenge FDA's January 3, 2023, approval of modifications to the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone.[1] On April 7, 2023, this Court declined to preliminarily enjoin FDA from enforcing or applying any requirement of mifepristone's REMS. Order at 26-27. But the Court preliminarily enjoined the agency from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 Risk Evaluation and Mitigation Strategy [(REMS)] under 21 U.S.C. § 355-1 in Plaintiff States." Order at 30.

Shortly before this Court entered its order, the United States District Court for the Northern District of Texas entered an order invoking 5 U.S.C. § 705 to stay the approval of the new drug application and abbreviated new drug application for mifepristone. *See Alliance for Hippocratic Medicine v. FDA*, 2:22-cv-00223-Z, Dkt. 137 (Apr. 7, 2023). That court stayed its order for seven days to give FDA

[1] This motion uses the term "mifepristone" to refer to drug products that are approved for medical termination of early pregnancy, in both brand name and generic form. FDA has separately approved another manufacturer's drug, Korlym, which has mifepristone as its active ingredient and is approved for the treatment of Cushing's syndrome. This litigation, including the Court's order, does not affect Korlym or its generic.

time to seek relief from the United States Court of Appeals for the Fifth Circuit, and FDA is seeking an emergency stay pending appeal. But if the Texas district court's order takes effect, the order would—of its own force and without any further action by FDA—stay the effectiveness of FDA's prior approvals of mifepristone nationwide. *See id.*

The result of that order appears to be in significant tension with this Court's order prohibiting FDA from "altering the status quo and rights as it relates to the availability of Mifepristone" in Plaintiff States. Order at 30. The Court did not address the interaction between the two orders, presumably because they were issued less than 20 minutes apart. To ensure that Defendants comply with all court orders in these unusual circumstances, Defendants respectfully request that this Court clarify their obligations under its preliminary injunction in the event that the *Alliance* order takes effect and stays the approval of mifepristone.

April 10, 2023

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CERTIFICATE OF SERVICE

I hereby certify that, on April 10, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Noah T. Katzen

NOAH T. KATZEN